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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,293	10/23/2000	Stephen T. Kuehn	S16.12-0101	1653

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EXAMINER

NGUYEN, VI X

ART UNIT PAPER NUMBER

3734

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/694,293

Applicant(s)

KUEHN ET AL.

Examiner

Victor X. Nguyen

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7,10-13 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) 2,6,8,9,14,16,17,19,21,22,27 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 18,20,23-26 and 28 is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7,10-13 and 30-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/15/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Leveen (3,916,908). Leveen discloses in Figs. 1-2, a surgical instrument having the limitations as recited in claim 1, including: one pair of arms (3,3'), where at least one arm of the pair of arms has at least one pointed member (13) that is capable for fastening two adjacent tissue heart valve leaflets, and where the arms pivot from one orientation to a gripping position (see col. 2, lines 29-40) which the paired arms being adjacent and directed toward each other at best seen in fig. 2.

Regarding the intended use of the pair of arms for fastening two adjacent tissue heart valve leaflets, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the arms of Leveen would have been capable of performing the use as claimed. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 1,3-5,7,10-13 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Middleman et al (5,601,572).

Art Unit: 3734

Middleman et al disclose in Figs. 8-4c, a surgical instrument having the limitations as recited in claims 1 and 3, including: one pair of arms (21,23), where at least one arm of the pair of arms has at least one pointed member (31) that is capable for fastening two adjacent tissue heart valve leaflets, and where the arms pivot from one orientation to a gripping position which the paired arms being adjacent and directed toward each other at best seen in fig. 8-4a. Regarding a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the arms of Middleman would have been capable of performing the use as claimed. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). As to claims 4-5,7,10-13, a system further has a catheter or a cannula (25 or 159) that is inherently capable for deployment into a human heart, where the paired arms (21,23) extend toward each other when the fastener is in a gripping position, and where the arms flex to a low profile position to fit within the catheter, where the fastener further has a shaft that is releasably holding the fastener of the shaft

Regarding claims 30-33, Middleman et al disclose in Fig.8-9, where a fastening member comprises a cap (103 which is being slidable relative to a gripper (102) , and where the gripper comprises a plurality of arms (102,106) from a pivot, where each arm has a spike (104), and where the cap comprises a locking mechanism to lock the gripper in a lock position (see fig. 8-9), and where the fastener further has a flexible rod (see fig. 8-7b) which has a disengaging mechanism which permits the rod to releasably holding the cap.

Allowable Subject Matter

2. Claims 18,20,23-26 and 28 are allowed.

The following is a statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses or suggests where a heart valve repair instrument comprising a cap that is located distal to the pivot and the pivot is located distal to a shaft, where a flexible rod connects to the cap to provide for movement of the cap relative to the pivot of the gripper and the shaft by pulling the flexible rod, where the cap has an opening that can be positioned over the pivot to lock the arms in a closed position.

Response to Arguments

3. Applicant's arguments filed 5/16/2006 have been considered but are moot in view of new ground(s) of rejections. Applicant is asked to please refer to the modified prior art rejections above where examiner addresses applicant's concerns regarding prior art rejection.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 3734

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victor X Nguyen
Examiner
Art Unit 3734



VN
8/16/2006



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER